

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION**

IN THE MATTER OF: SEARCH OF  
INFORMATION ASSOCIATED WITH E-  
MAIL ACCOUNTS UTILIZING THE  
DOMAIN NAME "FSCLABS.COM" THAT  
IS STORED AT PREMISES CONTROLLED  
BY RACKSPACE US, INC.

Case No. 3:10-mj-188

**FILED UNDER SEAL**

IN THE MATTER OF: SEARCH OF  
INFORMATION ASSOCIATED WITH E-  
MAIL ACCOUNTS UTILIZING THE  
DOMAIN NAME "FSCPEDIATRICS.COM"  
THAT IS STORED AT PREMISES  
CONTROLLED BY GOOGLE, INC.

**AFFIDAVIT IN SUPPORT OF AN APPLICATION FOR A SEARCH WARRANT**

I, George Scavdis, being first duly sworn, hereby depose and state as follows:

**INTRODUCTION AND AGENT BACKGROUND**

1. I make this Affidavit in support of an application for search warrants pursuant to 18 U.S.C. §§ 2703(a), 2703(b)(1)(A) and 2703(c)(1)(A) to:

a. Rackspace US, Inc. ("Rackspace"), a provider of e-mail hosting services headquartered at 5000 Walzem Road, San Antonio, Texas 78218, requiring Rackspace to disclose to the Government records and other information in its possession pertaining to the subscriber or customer associated with the accounts it hosts that are associated with

the "fscslabs.com" e-mail domain name. The information to be searched is described in the following paragraphs and in Attachment A.

b. Google, Inc. ("Google"), a provider of e-mail hosting services headquartered at 1600 Amphitheatre Parkway, Mountain View, California 94043, requiring Google to disclose to the Government records and other information in its possession pertaining to the subscriber or customer associated with the accounts it hosts that are associated with the "fscpediatrics.com" e-mail domain name. The information to be searched is described in the following paragraphs and in Attachment B.

2. I am a Special Agent with the United States Food and Drug Administration's Office of Criminal Investigations, and have been since 2009. Prior to that, I was a Special Agent with other federal law enforcement agencies including the United States Secret Service and the U.S. Agency for International Development, Office of the Inspector General. During my employment with the aforementioned agencies, I have received several training classes pertaining to internet investigations, and have conducted many investigations that required me to access, retrieve, and review e-mails from stored servers.

3. The facts in this Affidavit come from my personal observations, my training and experience, and information obtained from other agents and witnesses. This affidavit is submitted for the limited purpose of establishing probable cause and does not set forth all of my knowledge about this matter or the entirety of the investigation.

4. Based on my training and experience and the facts set forth in this Affidavit, there is probable cause to believe that criminal violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), specifically 21 U.S.C. § 331(a) and (k) and § 333, have been committed by FSC Laboratories, Inc., and its wholly-owned subsidiary, FSC Pediatrics, Inc.

There is also probable cause to search the information described in Attachments A and B for evidence of these crimes as described in Attachment C.

### PROBABLE CAUSE

#### **A. Statutory and Regulatory Background**

5. The Federal Food, Drug, and Cosmetic Act ("FDCA"), among other things, governs the interstate distribution of drugs for human use. The FDCA and its implementing regulations prohibit the distribution of any new drug in interstate commerce until the sponsor or manufacturer of that new drug receives approval from the United States Food and Drug Administration ("FDA"), based on an intensive application and review process. 21 U.S.C. § 355.

6. The FDCA requires that the sponsor of a new drug submit a New Drug Application ("NDA") to the FDA, which identifies all of the proposed uses of the drug intended by that sponsor, together with the proposed labeling for those uses, and data generated in randomized and well-controlled clinical trials that demonstrate to the FDA's satisfaction that the drug would be safe and effective for those intended uses. 21 U.S.C. §§ 331(d) and 355(b).

7. Until FDA approves the NDA, including the proposed labeling, the FDCA prohibits the sponsor from introducing the new drug into interstate commerce. 21 U.S.C. § 355(a). Only after the FDA approves the application is the sponsor permitted by law to promote and market the drug, and then only for the medical conditions of use specified in the approved labeling. Uses not approved by the FDA, and not included in the drug's approved label, are known as "off-label" uses.

8. Under the FDCA, if the sponsor of a drug wants to market that drug for an unapproved or off-label use, the sponsor is required to first submit to the FDA each additional proposed use, together with sufficient evidence to demonstrate that the drug is safe and effective

for each additional proposed therapeutic use. The sponsor may not lawfully label, market, or promote the drug for any new intended use without the prior approval of FDA.

9. The FDCA provides that a drug is misbranded if, among other things, the labeling does not bear adequate directions for its use. 21 U.S.C. § 352(f)(1). Adequate directions for use cannot be written for indications or uses for which the drug had not first been found by the FDA to be safe and effective through well-controlled clinical studies. Drugs that are promoted for unapproved, off-label, uses are therefore deemed to be misbranded as a matter of law.

10. The FDCA makes it a federal crime to cause the distribution in interstate commerce of a misbranded drug, as well as any act which causes a drug held for sale to become misbranded after traveling in interstate commerce. 21 U.S.C. § 331(a) and (k); 21 U.S.C. § 333.

**B. Off-Label Marketing by FSC Laboratories, Inc. and FSC Pediatrics, Inc.**

11. FSC Laboratories, Inc. and its wholly-owned subsidiary, FSC Pediatrics, Inc., (collectively "FSC") promote, market, and distribute in interstate commerce the prescription drug, Primsol (chemical name: trimethoprim hydrochloride). Primsol is a synthetic antibacterial drug and is dispensed as a bubble-gum-flavored liquid solution.

12. FSC's principal place of business is located within the Western District of North Carolina, at 6000 Fairview Road, Suite 600, Charlotte, North Carolina 28210. The management team includes:

- a. Peter W. Steelman of Charlotte, North Carolina, President and Chief Executive Officer of FSC Laboratories, Inc. and the President and principal shareholder of FSC Pediatrics, Inc.;
- b. James E. Flynn of New York, New York, Chairman of FSC Laboratories, Inc.;

- c. Sara H. Steelman, M.D., of Charlotte, North Carolina, Peter Steelman's wife and FSC's Medical Affairs Officer; and
- d. Cantey L. Land, Ph.D., of Charlotte, North Carolina, Project Manager for FSC Laboratories, Inc.

13. Primsol is FDA-approved for the treatment of acute otitis media (ear infections) in children and uncomplicated urinary tract infections in adults. Any other use of Primsol is an unapproved, off-label use.

14. FDA records reflect that in 2005, FSC initiated inquiries with the FDA about the possibility of obtaining FDA approval for the treatment of pediatric urinary tract infections. In February 2006, during a teleconference meeting, FDA told FSC's management team (including FSC Laboratories' President and Chief Executive Officer Peter W. Steelman), that data the company had submitted in support of FDA approval for treating pediatric urinary tract infections was inadequate to demonstrate the drug's safety and efficacy for that use. This was the second time that FDA had rejected a pediatric UTI indication for Primsol. In 1997, FDA had rejected a previous request for the indication from the drug's previous promoter, Ascent Pharmaceuticals.

15. In November 2009, two former FSC district sales managers filed a *qui tam* action pursuant to the Federal False Claims Act against FSC Laboratories, FSC Pediatrics, and Peter Steelman in the U.S. District Court for the Southern District of Ohio alleging that the defendants caused false payment claims to be presented to various federal healthcare programs related to Primsol. *United States ex rel. Myers and Vlcek v. FSC Laboratories, Inc. et al.*, No. 2:09-cv-1043 (S.D. Ohio). This action remains under seal. From information the relators have provided, as well as additional interviews I have conducted with former employees of FSC, I have learned that since at least 2008, FSC has been actively marketing and promoting Primsol for uses that

have not been approved by FDA. I have learned through my investigation and through internal FSC e-mails provided to me by the relators (some of which are set forth below) that FSC has promoted the prescribing of Primsol for, among others, the following off-label uses:

- a. For urinary tract infections ("UTIs") in children; and
- b. As a long-term prophylaxis for children's vesicoureteral urinary reflux ("VUR")<sup>1</sup>;
- c. For children younger than 6 months; and
- d. For Methicillin Resistant *Staphylococcus aureus* ("MRSA"), especially "Community Associated MRSA" or "CA-MRSA" a bacterial skin infection mostly affecting children and adolescents.

16. In fact, the relators have estimated that approximately 80-90 percent of sales calls undertaken by FSC personnel were to promote Primsol's off-label usage to pediatric nephrologists and pediatric urologists, who – as specialists in the pediatric genitourinary tract – are extremely unlikely to be prescribing Primsol to treat ear infections, Primsol's only approved use in children.

17. The relators have provided the Government with a document FSC prepared entitled "PRIMSOL SOLUTION: selling points," and is believed to have been distributed to FSC sales representatives by FSC management. The guide instructs sales personnel to market Primsol to physicians in several "targeted specialties" as follows:

- a. "Urology: Targeted infections are UTI and prophylaxis. (Prophylaxis: Preventative measure; also known as suppression.) *Although we do not have a*

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<sup>1</sup> Vesicoureteral reflux ("VUR") is the backup of urine from the bladder into the tube that carries urine from the kidney to the bladder (ureter) during urination. VUR may result in urine reflux into the renal pelvis, causing distention and kidney damage. In children, this condition is usually caused by a congenital anatomical abnormality.

*prophylaxis indication this is where urologist[s] use SMX [sulfa] + TMP [trimethoprim – Primisol] ....” [emphasis added].*

- b. “VUR: When a child is diagnosed as having vesicoureteral urinary reflux (VUR) a urologist will put the child on a preventative antibiotic, often times SMX=TMP. The dose is usually cut in half, given once a day for 18-24 months. It makes sense to use the safer product, especially long term use ... Dr. Nguyen (He goes by Dr. Bob), pediatric urologist at Boston Children’s (Harvard), uses Primisol prophylaxis in neonates (newborns.)”
- c. “Product Referral: Once you get a urologist on board prescribing Primisol ask for his/her approval to tell pediatricians of their use and success w/Primisol.”
- d. “ENT (Otolaryngologists): Targeted infections are sinus and ear”
- e. “Pediatricians: This particular specialty is so general, your details could go in several directions. It is important you stay focused and listen well to what the physician tells you when you begin probing. *UTI: Obviously we do not have the UTI indication in pediatrics, however this is a clear and present way, in the usual pediatrician’s mind, to use TMP alone.* This will probably be the first place a pediatrician will place TMP alone in their antibiotic arsenal.” [emphasis added].

18. Likewise, the guide instructs sales representatives to follow-up with physicians who object that Primisol is “[n]ot indicated for the infection I’m thinking about,” with the following questions that promote off-label use: “What infection(s) are you thinking about using Primisol for? What are you currently prescribing for that infection? Is that product currently

indicated for the infection you're thinking about? Hypothetically, would you prefer a safer option to that product you're using?"

19. According to the relators, at an FSC training class in October 2008, which they attended, FSC District Manager Elizabeth Moss instructed newly-hired sales representatives, "I'm not telling you to sell off-label, but sell off-label." FSC Laboratories' President and Chief Executive Officer, Peter W. Steelman, was present at the time, and jokingly commented that maybe he should walk out of the room (so he would not hear her instructing sales representatives to violate the FDCA). He, in fact, continued to stay in the room, however.

20. The relators also told me during interviews that during company conference calls, Steelman would discuss "how to get [doctors to write] prescriptions for MRSA" and "what [FSC] was doing for pediatric urologists." The relators also told me that Steelman explained to them that FSC was not pursuing FDA approval for these uses because obtaining such approval would be too expensive.

21. During October 2008, the relators manned an FSC promotional booth during the annual meeting of the American Academy of Pediatrics in Boston, Massachusetts. Primsol was the only antibiotic with a promotional booth in the pediatric urology section of the conference.

22. In the course of the investigation, I interviewed a former FSC sales representative, Eric Levin, who sold Primsol. Levin stated that he received regular direction from his district sales manager, Rodney Kennerly (e-mail address: [rodneykennerly@fscpediatrics.com](mailto:rodneykennerly@fscpediatrics.com)), to "go after" pediatric UTIs and MRSA. Furthermore, Levin relayed to me a conversation he once had with Steelman in which Steelman praised Levin for his success in promoting Primsol for MRSA and pediatric UTIs.



**C. Use of “fsclabs.com” and “fscpediatrics.com” Domain Name E-mails To Market and Promote Off-Label Uses**

23. Among the internal FSC documents the relators provided to the Government as evidence of unlawful Primsol promotion were several electronic mail messages sent using FSC e-mail addresses, including e-mails to and from employees with e-mail addresses utilizing the “fsclabs.com” domain name and the “fscpediatrics.com” domain name.

24. For example, in an e-mail exchange beginning on May 28, 2009, and continuing until May 29, 2009, FSC President and CEO Peter Steelman, using the e-mail address “petersteelman@fsclabs.com,” responded to a sales representative’s question about the recommended dose of Primsol for the off-label use of prophylaxis of pediatric UTI’s. The sales representative, Melissa Rosenthal sent the inquiry via the e-mail address (melissarosenthal@fscpediatrics.com) to her sales manager, Chad Myers (chadmyers@fscpediatrics.com). Myers then forwarded on the request to Steelman.

25. In that e-mail exchange, Sales Representative Rosenthal boasted that the question regarding recommended dose for off-label use originated from the Nationwide Children’s Hospital Pediatric Urology Department and “was the result of working closely with the office staff and nurses. I’m in there all of the time and every time I go in there I detail everyone and send back info for Dr. Koff.” Based upon my investigation and Primsol’s FDA approval only for treatment of acute otitis media (ear infections) in pediatric patients -- as well as the contents of the e-mail itself – the FSC sales representative’s presence at a Pediatric Urology Department appears to be for the purpose of promoting Primsol for off-label uses.

26. CEO Steelman responded to the above e-mail chain from his fsclabs.com account, stating “We have heard that other pediatric urologists prescribe anywhere between 2mg and 5mg per kg for UTI prophylaxis.” As Steelman well knew, Primsol is not FDA approved for either

pediatric UTIs or prophylaxis. Indeed, as explained above, FDA documentation reveals that in 2006, Mr. Steelman was personally told by FDA that additional study was necessary before such indications would be considered safe and effective.

27. As another example, Steelman utilized his fsclabs.com e-mail account in March 2009, to urge FSC Sales Representative Allison Stewart – e-mail address: allisonstewart@fscpediatrics.com – to call on two pediatric urologists at Riley Children’s Hospital in Indianapolis, Indiana. After Stewart assured Steelman that she had been doing so (along with other affiliated pediatric urologists), Steelman responded, “Sounds like you are all over it. These prescribers would be a great base for you if they would just see the light and adopt the product(s),” which is believed to be a reference to Primisol.

28. Steelman also personally promoted Primisol to pediatric urologists for off-label uses through his fsclabs.com e-mail account. On July 10, 2008, Steelman e-mailed Dr. Eugene Minevich, president of the American Association of Pediatric Urologists and a pediatric urologist at Children’s Hospital in Cincinnati, Ohio. Before asking Dr. Minevich if an FSC sales manager could call on him about Primisol, he reminded Dr. Minevich of a “significant unrestricted education grant FSC will be making to Cincy Children’s.” This e-mail chain suggests that Steelman and FSC Laboratories use grants and contributions as a method to gain access to practitioners whom FSC targets for the off-label promotion of Primisol.

29. As another example, in June 2009, a series of e-mails were circulated between Steelman (using e-mail address petersteelman@fscpediatrics.com), FSC Project Manager Cantey Land (canteyland@fscpediatrics.com), and several others utilizing the fscpediatrics.com e-mail domain name providing a list of “doctors that attended the National Pediatric Urology meeting in Chicago” and noting that “we [FSC] paid a lot of money to support this meeting ... tell your reps

to make it a point to find the doctors in their territory that attended. . . .” Again, this e-mail chain suggests that FSC Laboratories uses grants and contributions as a method to gain access to practitioners whom are targeted for the off label promotion of Primisol.

30. Steelman was not the only FSC officer who utilized the fsclabs.com e-mail domain to send or receive messages in an effort to further the unlawful promotion of Primisol for unapproved uses. For example, on June 9, 2009, FSC’s Project Manager, Cantey Land, Ph.D., utilized her e-mail account (“canteyland@fsclabs.com”) to send a message to one of the relators to make sure that an FSC sales representative would be attending a pediatric infectious disease conference in Chicago. FDA has not approved Primisol to treat any pediatric infectious diseases.

31. FSC’s compliance officer, Karla Ham, whose job responsibility I understand to be assuring FSC’s compliance with the FDA (among other things) also utilizes the “fsclabs.com” e-mail domain name: “karlaham@fsclabs.com.”

32. Other employees also utilize the fscpediatrics.com e-mail domain to send or receive messages in an effort to further the unlawful promotion of Primisol for unapproved uses. FSC’s Director of Sales Operations, Leigh Jones, utilized the “fscpediatrics.com” on June 25, 2009, to send an e-mail to FSC’s four district managers and to its National Director of Sales, Jeff Mason, cautioning them that sales representatives’ purchases of the Sanford Guides be “very vague,” if more than one purchase was being made. The Sanford Guide to Antimicrobial Therapy is a privately published book that recommends treatments for various infectious diseases. Depending upon the version, it retails for \$16-40. Sanford Guides apparently suggest the use of Primisol to treat MRSA. Therefore, providing the Guide to physicians as a “gift” bolstered the credibility of FSC’s promotional message that Primisol was safe and effective for treating MRSA, notwithstanding the drug’s lack of FDA approval for that use.

33. FSC's National Director of Sales, Jeff Mason also utilized the "fscpediatrics.com" e-mail domain to send or receive messages in an effort to further the unlawful promotion of Primisol for unapproved uses. For example, on June 8, 2009, Steelman sent an e-mail to Mason at jeffmason@fscpediatrics.com, and other FSC management officials, that attached a list of pediatric urologists who attended the 58th Annual meeting of the Society of Pediatric Urology. Steelman cautioned in the e-mail that, "All reps should know this is for their use only and is not, under any circumstances, to be distributed outside FSC."

34. The above-described e-mails are a sampling of the e-mails provided by the relators to the Government in connection with their *qui tam* action. Based upon my review of all the e-mails and my interviews with current and former FSC employees, it appears that FSC officers and employees use e-mail (with both domain names "fslabs.com" and "fscpediatrics.com") to communicate internally about off-label marketing of Primisol and to communicate with health care providers to promote the off-label use of Primisol.

#### **D. Rackspace and Google E-mail Services and Parameters**

35. I have learned that Rackspace US, Inc. provides electronic mail hosting to the general public and to resellers who resell Rackspace's e-mail hosting services to the general public, allowing subscribers to register a personalized domain name, such as fslabs.com to their e-mail servers. Through the investigation, I have learned that the fslabs.com e-mail domain name resolves to e-mail servers maintained by Rackspace.

36. Rackspace has confirmed to the Government that it maintains approximately fifteen electronic mailboxes (although several mailboxes are empty) for the fslabs.com domain name at its facility in San Antonio, Texas.

37. Accordingly, e-mail sent or received by an fsclabs.com e-mail account is likely to be stored on Rackspace servers. In addition to the stored electronic communications (including retrieved and unretrieved e-mail for fsclabs.com), Rackspace is likely to also have information concerning subscribers and their use of Rackspace services, such as account access information, e-mail transaction information, and account application information.

38. In general, an e-mail that is sent to an fsclabs.com e-mail address is stored in the subscriber's "mail box" on Rackspace's servers until the subscriber deletes the e-mail. If the subscriber does not delete the message, the message can remain on Rackspace's servers indefinitely.

39. When a subscriber with an fsclabs.com e-mail account sends an e-mail, it is initiated at the user's computer, transferred via the internet to Rackspace's servers, and then transmitted to its end destination. Rackspace often saves a copy of the e-mail sent. Unless the sender of the e-mail specifically deletes the e-mail from the Rackspace server, the e-mail can remain on the system indefinitely.

40. A sent or received e-mail typically includes the content of the message, source and destination addresses, the date and time at which the e-mail was sent, and the size and length of the e-mail. If an e-mail user writes a draft message but does not send it, that message may also be saved by Rackspace but may not include all of these categories of data.

41. A Rackspace subscriber can also store files, including e-mails, address books, contact lists, calendar data, pictures, and other files, on servers maintained or owned by Rackspace.

42. I have learned that Google provides electronic mail hosting to the general public, allowing business clients to use a personalized domain name, such as fscpediatrics.com, that is

hosted by Google's e-mail servers. This enables companies to maintain e-mail addresses branded with their own domain name, but that are actually maintained and hosted by Google.

43. A mail exchanger record ("MX record") is a type of resource record in the Internet Domain Name System that specifies the mail server responsible for accepting e-mail messages on behalf of an e-mail recipient's domain. In short, the MX records of a domain name specify how and where e-mail should be routed.

44. On October 19, 2010, a MX records search for the domain name "fscpediatrics.com" resolved to the mailserver "ASPMX.L.GOOGLE.com" indicating that e-mail for recipients with an fscpediatrics.com e-mail address should be routed to that server. I have learned that ASPMX.L.GOOGLE.com is the internet name for the mail server utilized by Google for its "Google Apps" service, which provides e-mail hosting services to businesses.

45. Accordingly, e-mail sent or received by an fscpediatrics.com e-mail account is likely to be stored on Google's servers. In addition to the stored electronic communications (including retrieved and unretrieved e-mail for fscpediatrics.com), Google is likely to also have information concerning subscribers and their use of Google's services, such as account access information, e-mail transaction information, and account application information.

46. In general, an e-mail that is sent to an fscpediatrics.com e-mail address is stored in the subscriber's mailbox on Google's servers until the subscriber deletes the e-mail. If the subscriber does not delete the message, the message can remain on Google's servers indefinitely.

47. When a person with an fscpediatrics.com e-mail account sends an e-mail, it is initiated at the user's computer, transferred via the internet to Google's servers, and then transmitted to its end destination. Google often saves a copy of the e-mail sent. Unless the

sender of the e-mail specifically deletes the e-mail from the Google server, the e-mail can remain on the system indefinitely.

48. A sent or received e-mail typically includes the content of the message, source and destination addresses, the date and time at which the e-mail was sent, and the size and length of the e-mail. If an e-mail user writes a draft message but does not send it, that message may also be saved by Google but may not include all of these categories of data.

49. A Google Apps subscriber can also store files, including e-mails, address books, contact lists, calendar data, pictures, and other files, on servers maintained or owned by Google.

50. Most e-mail providers typically retain certain transactional information about the creation and use of each account on their systems. This information can include the date on which the account was created, the length of service, records of log-in times and durations, the types of service utilized, the status of the account (including whether the account is inactive or closed), the methods used to connect to the account, and other log files that reflect usage of the account. In addition, e-mail providers often have records of the Internet Protocol address ("IP address") used to register the account and the IP addresses associated with particular logins to the account. Because every device that connects to the internet must use an IP address, IP address information can help to identify which computers or other devices were used to access the e-mail account.

51. In some cases, e-mail account users will communicate directly with an e-mail service provider about issues relating to the account, such as technical problems, billing inquiries or complaints from other users. E-mail providers typically retain records about such communications, including records of contacts between the user and the provider's support

services, as well as records of any actions taken by the provider or user as a result of the communications.

52. Based on the foregoing, I have probable cause to believe additional evidence of criminal violations of the FDCA exists and is stored in the FSC electronic mailboxes utilizing the “fscslabs.com” domain name, located on e-mail servers maintained by Rackspace and utilizing the “fscpediatrics.com” domain name, located on e-mail servers maintained by Google.

#### INFORMATION TO BE SEARCHED AND THINGS TO BE SEIZED

53. I anticipate executing this warrant under the Electronic Communications Privacy Act, in particular 18 U.S.C. §§ 2703(a), 2703(b)(1)(A), and 2703(c)(1)(A), by using the warrants to require Rackspace and Google to disclose to the Government copies of the records and other information (including the content of communications) particularly described in Section I of Attachment C. Upon receipt of the information described in Section I of Attachment C, Government-authorized persons will review that information to locate the items described in Section II of Attachment C.

#### CONCLUSION

54. Based on the foregoing, I request that the Court issue the proposed search warrant.

55. This Court has jurisdiction to issue the requested warrant because it is “a court of competent jurisdiction” as defined by 18 U.S.C. § 2711. 18 U.S.C. §§ 2703(a), (b)(1)(A), and (c)(1)(A). Specifically, the Court is “a district court of the United States . . . that – has jurisdiction over the offense being investigated.” 18 U.S.C. § 2711(3)(A)(i).

56. Pursuant to 18 U.S.C. § 2703(g), the presence of a law enforcement officer is not required for the service or execution of this warrant.

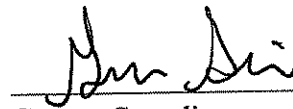


57. Pursuant to 18 U.S.C. § 3103a(b), I submit that there is reasonable cause to believe that immediate notification to FSC of the execution of the search warrants may have an adverse result (as is defined in 18 U.S.C. § 2705), specifically, the destruction of or tampering with evidence. FSC is a small privately held company, though the exact number of employees is unknown. To the extent that FSC even has a document retention policy, the parameters of that policy are unknown. As is set forth above, the documentary and electronic evidence discovered to date reveals a scheme to market Primisol for unapproved uses which permeates the entire corporate structure and may result in individual criminal liability for certain individuals. If the existence of the warrants is made known, I submit that there is reasonable cause to believe that FSC and its management will immediately recognize the investigatory significance of the warrants, which may result in the destruction of documents and information, including electronic evidence. Furthermore, notification to FSC of the execution of the search warrants may cause FSC and its management to be concerned about the possibility of civil, as well as criminal liability, and may lead to the destruction of or tampering with evidence relevant to the *qui tam* action, which remains under seal. Therefore, in order to allow the United States sufficient time to receive, process and review the disclosed e-mails, I request that the notification of the execution of the warrants be delayed for a period of 60 days, until December 24, 2010.

58. I further request that the Court order that all papers in support of this application, including the affidavit and search warrant, be sealed until further order of the Court. These documents discuss an ongoing criminal investigation that is neither public nor known to all targets of the investigation. Accordingly, there is good cause to seal these documents because their premature disclosure may seriously jeopardize the investigation. Moreover, this Affidavit

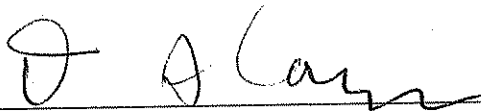
discusses the existence of a *qui tam* action that has been filed in another judicial district and remains under seal.

Respectfully submitted,



George Scavdis  
Special Agent  
FDA, Office of Criminal Investigations

Subscribed and sworn to before me on this 25 day of October, 2010:



David S. Cayer  
UNITED STATES MAGISTRATE JUDGE

## **ATTACHMENT A**

### **Property to Be Searched**

This Warrant applies to information associated with all electronic mail accounts and electronic mailboxes utilizing the "fsclabs.com" e-mail domain name that are stored at premises owned, maintained, controlled, or operated by RACKSPACE US, INC., a company headquartered at 5000 Walzem Road, San Antonio, Texas 78218.

## **ATTACHMENT B**

### **Property to Be Searched**

This Warrant applies to information associated with all electronic mail accounts and electronic mailboxes utilizing the "fscpediatrics.com" e-mail domain name that are stored at premises owned, maintained, controlled, or operated by GOOGLE, Inc., a company headquartered at 1600 Amphitheatre Parkway, Mountain View, California 94043.

## **ATTACHMENT C**

### **Particular Things to be Seized**

#### **I. Information to be disclosed by e-mail host provider:**

To the extent that the information described in the preceding Attachment is within the possession, custody, or control of the e-mail host provider, the provider is required to disclose the following information to the Government for each account, mailbox, or identifier listed in the preceding Attachment:

- a. The contents of all e-mails stored in the account, including copies of e-mails sent to and from the account, draft e-mails, the source and destination addresses associated with each e-mail, the date and time at which each e-mail was sent, and the size and length of each e-mail;
- b. All records or other information regarding the identification of the account, to include full name, physical address, telephone numbers, and other identifiers, records of session times and durations, the date on which the account was created, the length of service, the types of service utilized, the IP addresses used to register the account, log-in IP addresses associated with session times and dates, account status, alternative e-mail addresses, methods of connecting, log files, and means and source of payment (including any credit or bank account number);
- c. All records or other information stored by an individual using the account, including address books, contact and buddy lists, calendar data, pictures, and files;

- d. All records pertaining to communications between the e-mail host provider and any person regarding the account, including contacts with support services and records of actions taken.

## **II. Information to be seized by the Government:**

All information described above in Section I that constitutes fruits, evidence, and instrumentalities of violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, involving FSC Laboratories, Inc. or FSC Pediatrics, Inc. (including any of their officers, employees, or agents) since January 1, 2006, including, for each account or identifier listed in the preceding Attachment, information pertaining to the following matters:

- a. Primsol (trimethoprim hydrochloride oral solution);
- b. Use of Primsol for treating anything other than acute otitis media in children and uncomplicated urinary tract infections in adults;
- c. Training provided to FSC officers, agents, or employees responsible for the sales, marketing, promotion, or regulatory status of Primsol;
- d. The safety and efficacy of Primsol, including adverse events associated with its use;
- e. Products that commercially compete with Primsol, including but not limited to Bactrim (trimethoprim and sulfamethoxazole);
- f. Communications between FSC and any state or federal governmental agency, including but not limited to the FDA, the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, and any state healthcare program, including Medicaid, regarding Primsol.

- g. Visits or other interactions by sales representatives, sales calls, or meetings with physicians by officers, employees, or agents of FSC regarding Primisol.
- h. Scientific or clinical studies regarding Primisol;
- i. Regulatory status and approval of Primisol;
- j. FSC interactions with Professional medical associations or patient advocacy groups regarding Primisol, including but not limited to the American Association of Pediatric Urology;
- k. FSC internal meetings, including but not limited to Board of Directors meetings, where Primisol was discussed;
- l. Funding provided to any health care practitioner, consultant, and any other person involving Primisol;
- m. Continuing medical education programs, promotional speaker programs, and peer-to-peer programs regarding Primisol; and
- n. Records relating to who created, used, or communicated with the account or identifier, including records about their identities and whereabouts.